To: Beck, Nancy[Beck.Nancy@epa.gov]; Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]; Wise, Louise[Wise.Louise@epa.gov]; Jakob, Avivah[Jakob.Avivah@epa.gov]
From: Dunton, Cheryl
Sent: Fri 8/4/2017 1:48:28 PM
Subject: RE: Press inquiry on long term tox studies for pesticides

Great thanks.

From: Beck, Nancy
Sent: Friday, August 04, 2017 9:48 AM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: RE: Press inquiry on long term tox studies for pesticides

Looks ok to me. thanks.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Dunton, Cheryl
Sent: Friday, August 4, 2017 8:23 AM
To: Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: Press inquiry on long term tox studies for pesticides

See incoming from Carey Gillam and our response below. Rick approved. Let me know if you have questions/comments before this goes to OPA. Thanks.

INCOMING

I need clarity on an issue that continues to percolate in this glyphosate/Roundup debate. Does the EPA **require** long term toxicity studies for full formulated pesticide products such as Roundup or only for the active ingredients in those products? You probably are aware that many people make this assertion but the EPA information on this topic posted on various web pages is a bit ambiguous. Could you please provide clarification on this issue?

RESPONSE

EPA does not routinely require long-term toxicity studies for pesticide product formulations. EPA does, however, require data on acute and long-term toxicity for all registered active ingredients, as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA carefully evaluates the hazard potential for each active ingredient.

For formulated end-use products, EPA requires a battery of acute toxicity studies to support the registration of each product. Determination of acute oral, dermal, eye, and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide active ingredient or end-use formulation. These data provide information on health hazards likely to arise when applying the product or when exposed soon after application. Under FIFRA, subchronic and chronic toxicity tests are examples of long-term toxicity tests required for active ingredients.

Additionally, all inert ingredients in pesticide products, including those in an inert mixture that may be added to other approved pesticide products, must be approved for use by EPA. As a part of EPA's evaluation of a pesticide product, the product's composition is examined to verify that all of the inert ingredients proposed for use in the pesticide formulation have been approved by EPA. Just as with individual inert ingredients, each component of an inert mixture must be supported by a battery of toxicity data and must be approved for use by EPA.

The hazard potential of a formulated pesticide product is assessed through evaluation of the relative toxicity of the individual inert ingredients and pesticide active ingredients. If there are data to indicate risk for a formulated mixture, EPA evaluates the potential effects in our risk assessments. The human health risk assessment process is conservative in that maximum legal use rates for applicators and maximum legal residue levels for dietary exposure assumptions are used, thus ensuring that when a pesticide is used according to the label, people are well protected.

From: Daguillard, Robert
Sent: Thursday, August 03, 2017 4:28 PM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Sisco, Debby <Sisco.Debby@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Lantz, Tracy <Lantz.Tracy@epa.gov>
Subject: CHERYL/OPP: question on formulated product testing

Good afternoon everybody.

Can we help Carey? Deadline COB tomorrow (Friday).

Thanks, R.

From: Carey Gillam
Sent: Thursday, May 18, 2017 10:50:20 AM
To: Milbourn, Cathy; Daguillard, Robert
Subject: question on formulated product testing

Greetings guys - hoping you both are doing well. I need clarity on an issue that continues to percolate in this glyphosate/Roundup debate. Does the EPA **require** long term toxicity studies for full formulated pesticide products such as Roundup or only for the active ingredients in those products?

You probably are aware that many people make this assertion but the EPA information on this topic posted on various web pages is a bit ambiguous.

Could you please provide clarification on this issue?

Best regards,

Carey Gillam